NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC- neomycin sulfate and polymyxin b sulfate and bacitracin zinc ointment BUTLER ANIMAL HEALTH SUPPLY, LLC DBA COVETRUS NORTH AMERICA

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment (Sterile) -VETERINARY

ANADA 200-553, Approved by FDA

DESCRIPTION:

Each gram contains: polymyxin B sulfate 10,000 units, bacitracin zinc 400 units, neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base) in a white petrolatum base, q.s.

ACTIONS:

Polymyxin B is one of a group of closely related substances produced by various strains of <u>Bacillus polymyxa</u>. The activity of polymyxin B is sharply restricted to gram-negative bacteria. Neomycin, isolated from <u>Streptomyces fradiae</u>, has antibacterial activity <u>in vitro</u> against a wide range of gram-negative and gram-positive organisms. Bacitracin, an antibiotic substance derived from cultures of <u>Bacillus subtilis</u> (Tracy), exerts antibacterial action <u>in vitro</u> against a variety of gram-positive and a few gram-negative organisms.

INDICATIONS:

This product is indicated for the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to one or more of the antibiotics contained in the ointment.

Laboratory tests should be conducted including <u>in vitro</u> culturing and susceptibility tests on samples collected prior to treatment.

PRECAUTIONS:

If irritation develops discontinue treatment with this drug. If there is no response to treatment in 2 to 3 days, discontinue treatment and re-evaluate diagnosis. Prolonged use may result in overgrowth of nonsusceptible organisms, including fungi.

Care should be taken not to contaminate the applicator tip during administration of the preparation.

ADVERSE REACTIONS:

Adverse reactions, such as itching, burning, or inflammation may occur in animals sensitive to this product.

DOSAGE AND ADMINISTRATION:

Properly cleanse area to be treated. Foreign bodies, crusted exudates and debris should be carefully removed. Express a small quantity of ointment into the conjunctival sac beneath the lower eyelid three or four times daily. After application hold the eyelids shut for a short time so that a thin film of ointment covers the cornea.

HOW SUPPLIED:

NDC 11695-6841-3

Tube of 3.5 g (1/8 oz) with ophthalmic tip.

STORAGE:

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temp].

KEEP OUT OF REACH OF CHILDREN.

Not for Human Use.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Warning: Serious hypersensitivity (anaphylactic) reactions have been reported in cats within 4 hours of application of antibiotic ophthalmic preparations. Some of these reactions have resulted in death.

covetrus_®

Questions?

(855) 724-3461

Distributed by: Covetrus North America 400 Metro Place North Dublin, OH 43017

covetrus.com

HNPB00N REV. 0121 AH-071986-01

Principal Display Panel Text for Container Label:

Covetrus logo Reorder #071986

NDC 11695-6841-3

Neomycin and polymyxin B sulfates, and

bacitracin zinc ophthalmic ointment, USP

For veterinary use only ANADA 200-553, Approved by FDA

Sterile ophthalmic ointment Rx only Net Wt. 3.5 g (1/8 oz.)



Reorder #071986

NDC 11695-6841-3

Neomycin and polymyxin B sulfates, and bacitracin zinc ophthalmic ointment, USP

For veterinary use only

ANADA 200-553, Approved by FDA

Sterile ophthalmic ointment Rx only Net. Wt. 3.5 g (1/8 oz.)

Each gram contains:

Actives: Polymyxin B sulfate 10,000 units, bacitracin zinc 400 units, and neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base).

Inactive: White petrolatum, q.s.

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Usual dosage: See package insert for dosage information.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

See crimp of tube for Lot Number and Expiration Date.

FOR OPHTHALMIC USE ONLY. Not for human use. KEEP OUT OF

REACH OF CHILDREN. Restricted drug - use only as directed.

DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.

AH-071986-L-01 HNPBAAL REV: 0121



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Principal Display Panel Text for Carton Label:

Covetrus logo Reorder #071986

NDC 11695-6841-3

Neomycin and polymyxin B sulfates, and

bacitracin zinc ophthalmic ointment, USP

Sterile Ophthalmic Ointment For veterinary use only Rx only

Net Wt. 3.5 g (1/8 oz.) ANADA 200-553, Approved by FDA



NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

neomycin sulfate and polymyxin b sulfate and bacitracin zinc ointment

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:11695-6841
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<pre>polymyxin B sulfate (UNII: 19371312D4) (polymyxin B - UNII:J2VZ 07J96K)</pre>	polymyxin B	10000 [USP'U] in 1 g	
neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:116QD7X297)	neomycin	3.5 mg in 1 g	
bacitracin zinc (UNII: 89Y4M234ES) (bacitracin - UNII:58H6RW052I)	bacitracin zinc	400 [USP'U] in 1 g	

Inactive I	ngredients
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Ingredient Name	Strength
Petrolatum (UNII: 4T6H12BN9U)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11695-6841-3	1 in 1 CARTON			
1		3.5 g in 1 TUBE			

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANADA	ANADA200553	10/27/2021	

Labeler - BUTLER ANIMAL HEALTH SUPPLY, LLC DBA COVETRUS NORTH AMERICA (603750329)

Registrant - Akorn Operating Company LLC (117693100)

Establishment				
Name	Address	ID/FEI	Business Operations	
Akorn, Inc.		117696840	MANUFACTURE, ANALYSIS, STERILIZE, PACK, LABEL	

Revised: 10/2021 BUTLER ANIMAL HEALTH SUPPLY, LLC DBA COVETRUS NORTH AMERICA